EXHIBIT 1

SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

EMILY GRACE DOTEGOWSKI, ET AL., Plaintiffs, vs. ABBOTT LABORATORIES, INC., ET AL., Defendants.	Case No. CGC – 10-506794 ORDER RE: MOTIONS IN LIMINE AND TO BIFURCATE (PUNITIVE DAMAGES & STATUTE OF LIMITATIONS)

I heard extensive argument on motions in limine on December 9, 2014 and January 9, 2015 (the latter date included argument on the statute of limitations and an associated bifurcation motion). On January 9, I provided an additional 14 days for the parties to supply considered witness list for the proposed bifurcated trial on statute of limitations, such that the all issues would be deemed submitted by January 23, 2015.

This order reflects my rulings on all captioned motions. In short, there are various ruling on in limine motions, and I grant the motion to bifurcate on the statute of limitations.

Parties unsuccessful in seeking the exclusion of evidence may suggest a short limiting instruction.

Request for judicial notice are granted except (1) as indicated and (2) when they seek notice of items already in this court's file, (e.g., an opposition to defendant's summary judgment motion, a motion to clarify a court order, and a separate statement submitted in support of a summary judgment motion) in which case the requests are not useful.

No motions to seal are discussed here. The parties should alert me to any such unresolved motions.

Defendant's motions in limine

#1 **Bar Blume opinions**

Ruling: Deny

The papers suggest that defendant hopes to exclude these opinions of Dr. Cheryl Blume: (1) that as of 1998, information was available to defendant that established that Depakote was the most teratogenic mood stabilizer and/or anti-epileptic drugs (AED); (2) regarding the content that defendant should have placed on the Depakote label in 1998, including Blume's opinions that the label should have stated that Depakote should be used as a "last resort in women of childbearing age;" (3) as to her opinion on how prescribing doctors interpreted the Depakote label; and (4) as to her opinions regarding off-label promotion of Depakote.

Defendant argues that Blume failed to state in her report or deposition that Depakote was known to be more teratogenic than other mood stabilizers, and thus should not be allowed to testify as to such at trial. Not so. See e.g., Sejal Brahmbhatt Decl., Ex. 21, pp. 28-31. Defendant also argues that Blume's opinions regarding the teratogenic properties of Depakote are not supported by scientific materials. Not so. See defendant's own papers. Moving Papers 5:2-5 (4 studies). The existence of studies that contradict Blume's conclusion

is not pertinent in this context. Defendant claims that Blume should not testify as to what the contents of the Depakote label should have been because in her deposition testimony she admitted that the label could have informed users of studies showing Depakote to be more teratogenic than other AED's while also informing users of studies that show the opposite. Brian Mooney Decl., Ex. 1, 174:24 -175-2. Defendant cites *Bourelle v. Crown Equip. Co.*, 220 F.3d 532 (7th Cir. 2000). *Bourelle* is not useful; Blume is not offering another design; she is merely acknowledging the existence of information about Depakote that indicate that other drugs that treat the same conditions have less serious risks.

Defendant objects that Blume should not be allowed to testify as to her opinions on what the label should say because she is not a prescribing physician and cannot know how a prescribing physician might interpret a label. Dr. Blume is an expert in drug labels and is qualified to testify in any event.

Defendant objects that an expert witness cannot testify as to the contents of documents and may not testify as to legal opinions. Of course this is so, but I cannot on that basis preclude Blume from testifying regarding off-label promotional activities. Blume is an expert in federal drug regulation and has submitted a supplemental report regarding off label promotion of Depakote. Brahmbhatt Decl., Ex. 3. Dr. Blume is qualified to testify. Objections to legal opinions should be made as appropriate at trial.

#2 **Exclude Blume on comparative teratogenicity data**

Ruling: Testimony is to be limited to knowledge as of 1998 re Depakote, Tegretol, and lithium; comparative teratogenicity data re anti-epileptic drugs not admissible.

Defendant apparently seeks exclusion of comparative teratongencity data. In the alternative, defendant asks for exclusion to comparative teratongencity post-1998, and that I

limit any comparison to Depakote and Tegretol (which defendant claims were the only antiepileptic drugs that Dr. Kaplan used to treat bipolar disorder in 1997-98).

Defendant cites *Hain v. Johnson & Johnson* (N.J. Super Ct. June 12, 2013) ATL-L-8568 MT (unpublished). This does not suggest no plaintiff could ever prevail on a comparative teratogenicity argument as a matter of law. Defendant argues that plaintiff has not provided a sufficient evidentiary basis for her comparative teratogenicity theories, pointing out that none of plaintiff's experts has criticized Dr. Kaplan for using Depakote as opposed to lithium or Tegretol, and pointing to evidence indicating that Depakote was a good choice for Ms. Dotegowski's particular background. But Blume does present some basis for her opinions.

Argument confirmed the central issue: the extent to which Blume's opinions alluding to or relying on warnings for epilepsy, or other conditions not including e.g. spina bifida, are relevant. Generally speaking only risks of spina bifida are relevant in this case, and in the abstract the fact that Depakote was actually more dangerous than other epilepsy drugs (or not) would not be relevant at trial. Most of plaintiff's argument to the contrary is not clear. See Opposition at 11. Apparently, plaintiff contends that AED comparative teratogenicity is relevant because Abbott uses the same birth defect warnings for both conditions. But the issue is whether the label is misleading to one interested in prescribing the drug for mood disorders (or whatever plaintiff was suffering from); the fact that, for example, there might be a far safer drug for arthritis would not affect the prescriber's decision faced with plaintiff's conditions.

However, plaintiffs have suggested that Dr. Kaplan testified that as he prescribed the drug in this case he relied on the label's alerts on epilepsy-related risk. T47, 48, 50 (references

to the December and January arguments are to T and T2 respectively). If so this so, Blume may opine on these issues. Otherwise she may not.[1]

Defendant asks that I permit only references to pre-1998 Depakote-Tegretol teratogenicity data because with regard to "warnings, generally conduct should be measured by knowledge at the time the manufacture distributed product." *Feldman v. Lederle Labs*, 479 A.2d 374, 386 (1984). The parties agree on the legal standards. There is no basis for a *blanket* restriction of all post-1998 evidence: *some* might directly show that certain knowledge was knowable before 1998. This must be handled on a case by case basis, acknowledging that post-1998 evidence might under E.C. § 352 have a strong prejudicial effect unless it is clear that it truly refers to pre-1998 information. The § 352 risk can be ameliorated by employing the post-1998 documents to secure the pre-1998 data and presenting only the latter to the jury.

I take it the parties are in agreement that comparisons among all of the drugs used to treat bipolar disorder-- Depakote, Tegretol, and lithium—are relevant.

#3 **Exclude evidence re: Depakote labeling that post-dates 1998 (i.e., specifically label changes)**

Ruling: Grant.

While there may be no bar to this evidence in California, there is under New Jersey law. Evidence Code § 155 does not apply in the products liability context. *Ault v. Int'l Harvester Company*,13 Cal.3d 113, 120 (1974). Under New Jersey Law, however, the exclusion still applies. *Rosenberg v. Merck Sharp & Dohme Corp.*_2013 WL 1187916. Thus the issue whether this is a procedural issue or matter of substantive law. The plaintiffs seems to agree

[1] That is, I reject what I take to be plaintiff's alternative argument, which is that the total 'risk profile' of the drug is pertinent in this case. T 44.

(Opposition at 1) and I conclude that this is substantive, and so I should follows New Jersey law.

At argument (T2, 69) plaintiffs suggested there might be admissions on post 1998 labels which, if stripped of their context as labels, might be admissible. We can handle such issues at trial.

#4 **Exclude evidence of foreign product labels relating to Depakote (specifically Epilium)**

Ruling: Grant.

The issue presented here has been reviewed previously. *In re Viagra Products Liability Litigation*, 658 F.Supp.2d 950 (D.Minn., 2009), is directly on point. *In re Viagra* relied on *In re Seroquel Products Liability Litigation,* 601 F.Supp.2d 1313 (M.D.Fla. 2009). I agree with the court's decision to exclude "evidence of foreign regulatory actions and foreign label changes during their main case" because even if the information was relevant:

> its probative value is greatly overmatched by the jury confusion, waste of time, and unfair prejudice that would result if the Court were to allow Plaintiffs to introduce this evidence during their main case.
> To admit evidence about the foreign regulators' actions regarding Seroquel without providing context concerning the regulatory schemes and decision-making processes involved would strip the jury of any framework within which to evaluate the meaning of that evidence. Absent such background and context, a jury might be more inclined to abdicate its responsibilities and defer to the negative decisions of three foreign regulators regarding Seroquel's safety. Hence, precluding AstraZeneca from offering such contextual evidence would unfairly prejudice the company. On the other hand, allowing AstraZeneca to introduce this evidence would result in a series of "mini-trials" regarding the grounds for the decisions and the regulatory schemes of the three foreign countries involved. This would confuse the jury and waste everyone's time.

Plaintiffs cites e.g., *In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and PMF Products Liability*, 2011 WL 6740391 (unreported); *Mahaney ex rel. estate of Kyle v. Novartis Pharmaceuticals Corp.*, 835 F.Supp.2d 299, 318 (2011). While defendant here may well have

learned of certain facts and been on notice of certain dangers as a result of its acquisition of the drug from a European manufacturer,[2] it is not specifically *the label* that provides that notice—but the present motion in limine is only directed to the label. T 104, 106.

But were the label, as such, to be the basis of ascription of notice to defendant, the jury would have to be fully informed as to the background and processes of European labeling requirements, a furious and wasteful expenditure of time under § 352 (T: 110). And the risk that the jury would consider the European label as a fair model of what the US label ought to have looked like too—i.e., believing European labelling requirements are essentially those under US law—poses a very high risk under § 352. The balancing of § 352 plainly requires exclusion.

#5 **Re warnings that prenatal Depakote exposure could cause or contribute to developmental delay**

Ruling: Moot. Plaintiffs will not introduce the evidence.

#6 **Bar Abbot's promotional activities, distribution of promotional materials, and sales and marketing practices**

Ruling: Deny.

Abbot seeks to exclude activities directed to alleged off-label promotion, FDA untitled letters discussing certain promotional materials, and letters from the FDA's Division of Drug Marketing and Communications and Headquarters, based on three theories: relevancy; 352 prejudice; and impermissible character evidence. Plaintiffs tell me the challenged evidence is relevant to the applicability of the New Jersey presumption that a

[2] Actually it is not clear of what, exactly, plaintiff contends the European label put defendant on notice. It may be only that plaintiff wishes to impeach defendant if its witnesses say they did not know the drug was one of last resort—although it does not appear the European label said that. T111, 113, 116.

drug warning approved by the FDA is adequate; and to Dr. Kaplan's decision to prescribe Depakote.

As I have noted (September 23, 2014 Order) under New Jersey law a drug warning approved by the FDA is presumptively adequate, but the presumption may be rebutted by a showing that there was deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, or the defendant engaged in economically driven manipulation of the post-regulatory process. Sept. 23, 2014 Order, 8. One of Abbott's cases provides a nice outline of the law:

> The New Jersey Supreme Court indicated in *Perez* that in order to rebut the presumption, a plaintiff would have to show that the manufacturer engaged in deliberate concealment or nondisclosure of after-acquired knowledge of a harmful effect. *Perez*, 161 N.J. at 25, 734 A.2d 1245. The *Perez* court indicated that absent such a finding, "[f]or all practical purposes ... compliance with FDA standards should be virtually dispositive of such [failure to warn] claims." *Id.*
> The Appellate Division subsequently distinguished *Perez*, recognizing "an additional basis for overcoming the presumption of adequacy set forth in the PLA." *McDarby v. Merck & Co., Inc.*, 401 N.J.Super. 10, 63, 949 A.2d 223 (App.Div.2008). The *McDarby* court found that in the context of a pharmaceutical drug, claims of "economically-driven manipulation of the post-market regulatory process" were sufficient to rebut the presumption and permit a jury to decide whether a warning was adequate.
> One New Jersey court thereafter summarized the state of the law as follows:
>
> > Presently, the presumption of an adequate warning based on compliance with FDA regulations will be deemed rebutted only if the following proof is presented: (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects ("*Perez/Rowe* exception") or (ii) manipulation of the post-market regulatory process ("*McDarby* exception").... Although plaintiffs may present expert testimony in an attempt to rebut the statutory presumption ..., the presumption in favor of the adequacy of FDA-approved warnings will not be deemed rebutted unless plaintiff produce the type of evidence identified in *Perez, Rowe,* or *McDarby.*
>
> *Bailey v. Wyeth, Inc.*, 424 N.J.Super. 278, 312–13 (Law Div.2008). The New Jersey Supreme Court recently agreed that these are the only two methods of rebutting the presumption of an adequate warning. *Cornett*, 211 N.J. at 388 (indicating that "[t]o overcome this presumption," the plaintiff must show "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects," or "manipulation of the post-market regulatory process.") No other exceptions to the presumption have been recognized by the New Jersey courts.

Seavey v. Globus Med., Inc., No. CIV. 11-2240 RBK/JS, 2014 WL 1876957 *8. (D.N.J. Mar. 11, 2014).

Depakote was FDA approved for treatment of manic episodes associated with bipolar disorder, but was in this case used "off-label" for long-term maintenance of bi-polar disorder. While off-label use does not prevent the New Jersey presumption from arising, Abbott may have violated federal law through off-label promotion, which might block the presumption. Thus the challenged evidence is relevant and probative with respect to whether the New Jersey presumption arose, no particular prejudice appears, and if used in this way, the evidence is not inadmissible character evidence.

Plaintiffs contend that Abbott's marketing efforts reached Dr. Kaplan. Opposition, 10-11. Some of it might have, and Abbott appears to concede that if Dr. Kaplan's decision to prescribe Depakote was based on Abbott's promotional materials or activities, those materials or activities are relevant. Reply, 9.

The parties appear to agree that evidence of marketing activities post-dating Maryann's use of Depakote is irrelevant. As with other motions in limine, (e.g. #3) it may be that post 1998 documents contain good evidence of pre-1998 facts, and that will have to be handled on a case-by-case basis at trial. (T2: 74).

Finally I address more particularly defendants' view, pressed at argument (T2: 80), that only those promotional activities which reached Dr. Kaplan are relevant. Defense counsel urged me to re-read *Seavey*, which I have done. That was a summary judgment decision, and I see nothing that helps Abbott now. As plaintiffs noted, in *Seavey* "Plaintiff has produced no evidence showing that Globus marketed the device for use in an off-label manner...." *Seavey* at *9. Plaintiffs intend to produce that evidence in this case.

The rationale of *McDarby*, whence the post-market promotional exception to the PLA, does not tell us that the pertinent promotional activities must have affected the prescribing doctor. The point *McDarby* makes is the FDA does a bad job of regulating post market activities, unlike the presumably good job it does before drugs get to market, and accordingly bad post-market actions by drug manufactures are not entitled to same deference:

> Given these admitted flaws in the FDA's control over postmarket labeling in the years that Vioxx was on the market, we are unwilling to accept Merck's position that the presumption of adequacy of a prescription drug's label can be overcome only upon proof of deliberate concealment or nondisclosure.

McDarby v. Merck & Co., 401 N.J. Super. 10, 66, 949 A.2d 223, 258 (App. Div. 2008).

#7 **Exclude all of criminal plea agreement, civil settlement, and Corporate Integrity Agreement**

Ruling: Grant.

Plaintiffs desire this evidence to support their claim that Abbott encouraged the off-label use at issue here in 1997-1998. The settlement agreement cannot be offered to show that Abbott had a propensity to market Depakote for other off-label uses, and therefore marketed Depakote for a different off-label use in this case. See Evid. Code § 1101(a). In the abstract, it may be admissible to prove motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake. Evid. Code § 1101(b). In addition, evidence of habit or custom may be used to prove conduct in conformity with habit or custom, if otherwise admissible. Evid. Code § 1105.

This is not evidence of habit or custom. Custom or habit evidence involves a semi-automatic response to a repeated situation. *Bowen v. Ryan*, 163 Cal.App.4th 916, 926 (2006). It is not clear how, as Plaintiffs suggest, a 2012 settlement agreement shows that Abbott

knew its conduct was illegal in 1997 and 1998. See Opposition, 10-11. Perhaps the settlement agreement shows the marketing at issue in this case was part of a common scheme to promote Depakote for a variety of off-label uses. Even if there is some such relevance, this is substantially outweighed by the probability of undue prejudice if the settlement agreement, including the criminal plea and $1.5 billion payment, is put before the jury – Abbott's marketing of Depakote for behavioral problems in the elderly and schizophrenia is not at issue in this case. There is a very high risk that Abbott will be punished here because it settled a different case.

Plaintiffs suggest that the settlement agreement can be used to impeach Abbott's witnesses that have denied that Abbott engaged in any wrongdoing with respect to Depakote. Opposition, 12-14. Plaintiffs point to one deponent who denied that Abbott promoted Depakote off-label for schizophrenia, and one deponent who stated that she was not aware of the guilty plea. But because the settlement agreement should not come into evidence, there should be no reason to impeach Abbott's witnesses on their testimony relating to the settlement agreement. *Winfred D. v. Michelin North America, Inc.*, 165 Cal.App.4th 1011, 1034 (2008).

Finally, Plaintiffs contend that the settlement agreement will show that Abbott acted with a wanton and willful disregard for the persons who might be harmed, and therefore will be relevant to punitive damages. Opposition, 14. But this seeks to punish Abbott here for conduct for which it has settled its liability in a separate case. So it is irrelevant.

#8 **Exclude Blume testimony re: effect of defendant's alleged pharmacovigilance reporting violations had on the Depakote label.**

Ruling: Grant.

There is no basis to suggest any of the alleged failures or reporting violations had any effect on labels. Blume only testifies only that delays "may" have delayed getting information to the FDA, prescribers and patients. Thus this is speculation. None of the bases she cites supports her conclusion; many of the asserted reporting violations occurred after plaintiff's injury. While one document (Ex. 8) may be some support, there's no showing that Blume would rely solely on this to provide an opinion. Under § 352, the exceedingly minimal relevance is far outweighed by the serious risk that the jury would conclude Abbot was trying to withhold data from the FDA and seek to punish it for that behavior.

#9 **Exclude evidence that Abbott should have established a registry of pregnant women who were exposed to Depakote**

Ruling: Grant.

Abbott argues plaintiffs' experts offer only unfounded speculation with respect to whether additional knowledge was reasonably obtainable through a pregnancy registry. I agree.

Blume's expert report does little more than note that Abbott knew of problems with Depakote as early as 1982, but did not participate in a pregnancy registry until 1996 and as a result of that participation new risk data was added to Depakote labeling in 2006. Brahmbhatt Declaration, Ex. 1 at 68. Oakley goes farther, opining that Abbott could and should have initiated a registry in the early 1980s. Id., Ex. 7 at 3. Oakley's opinion that a registry could have been created is based on (1) his understanding of what a registry is – people with an exposure are followed up on, to look for health outcomes that may result from the exposure – and (2) the fact that registries had been used prior to the 1980s. Id., Ex. 7 at 7. Oakley has experience with registries generally. Id., Ex. 7 at 1-2. Notably,

Oakley does not say that a registry would have worked. Blume comes closer to implying as much, based on the eventual success of the 1996 registry. Id., Ex. 1 at 68. But this is no better than arguing that because one study worked another would have, or because one statistical sampling was valid, a different one is as well. Far more must be shown to establish the inferences of validity and feasibility. Without evidence that the registry would have worked, discussing Abbott's failure to create a registry is a speculative endeavor that will only serve to prejudice Abbott. Plaintiffs have not established the number of individuals that would have made a registry worthwhile, or whether such a critical mass could have been obtained at some earlier time.

#10 **Exclude reference to injuries or conditions suffered by others whose mother took Depakote; including adverse event reports (AERs) made by Abbott to the United States Food and Drug Administration**

Ruling: Grant.

Defendant agrees it is not here contesting the use of these items by experts. The parties also agree these reports are hearsay and cannot come in for the truth. Thus we move on to the extent to which these might come in for e.g. notice to Abbott of e.g., risk of spina bifida. Those that came in after Emily's birth are obviously irrelevant. But the issue in this case is notice that Depakote posed a *relatively* higher risk of adverse effects than comparable drugs, and nothing in these reports addresses that. Some of these reports are very poor evidence of notice, as they disclaim the suggestion of causation as between dosage and injury, or indeed that the drug is the cause of injury at all. The risk of prejudice under § 352 is very high indeed, as the jury might conclude these are formal reports of what Depakote in fact will do.

#11 **Exclude evidence regarding other lawsuits, claims, or investigations against Abbott**

Ruling: Moot. Plaintiff does not intend to introduce unless defendant 'opens the door.'

#12 **Bar evidence relating to thalidomide, dissimilar and unrelated drugs, or drugs withdrawn from the market generally**

Ruling: Moot. The motion has been resolved by stipulation filed January 13 2015.

#13 **Bar evidence relating to codes of business conduct, ethical guidelines, or similar standards promulgated by Abbott, the Food and Drug Administration, the Pharmaceutical Research and Manufacturers of America, or any other entity after 1998.**

Ruling: Grant.

These codes assertedly relate to the issue whether Abbot was reasonably prudent in its actions. But there is only the most tenuous link between these vague and abstract codes and the specific conduct which lies at the heart of plaintiff's case.

The specific language plaintiffs note is on its face so vague that much work would have to be done at trial, most of it speculation, to flesh them out so that they would actually bear on the issues the jury has to decide. See e.g., Sejal K. Brahmbatt, Ex. 1 at 12:8-20, 39:21-40:23, 41:8-16 (deponent worked at Abbott since 1989 and agrees that two broad and vague standards have been true throughout that time); Ex. 2 at 715 (deponent believes that the pharmacovigilance area holds itself to a high ethical standard and has not applied any different standards for the last 20 years); Ex. 3 at 155-56 (deponent opined that failure to act in accordance with unidentified guidelines of honesty, truthfulness, and the provision of fair and balanced information between 1978 and 1996 would have been unethical); Ex. 4 at 27-

28, 31 (deponent who worked at Abbott since 1995 opines in general terms with respect to Abbott's ethical standards without referencing any formal guidelines.) These codes and guidelines would invite the jury to determine whether Abbott had violated them, rather than address the core issues presented by this case; and it would be a waste of time to have them introduced and then explained. They are a distraction.

#14 **Exclude certain warning issues (beyond those relied on by Dr. Kaplan)**

Ruling: deny, but issue may arise when we discuss jury instructions on heeding presumption.

Abbott requests an order prohibiting Plaintiffs' counsel and their witnesses from introducing any expert opinion testimony, evidence, or argument concerning alleged defects in the FDA-approved label for Depakote beyond the scope of Dr. Kaplan's testimony as to the two specific labeling changes that Plaintiffs allege would have altered his prescribing decision, i.e., (1) the alleged failure of the label to warn that Depakote was a drug of last resort, and (2) the alleged failure of the label to warn that Depakote was more teratogenic than other mood stabilizers available at the time.

Abbott argues the only relevant warnings are those that Dr. Kaplan identified as warnings that would have changed his prescribing practices. Evidence pertaining to other alleged inadequacies in the warning is irrelevant, because Plaintiffs will not be able to prove that those defects proximately caused their injury. Motion, 5. Abbott asserts that no heeding presumption would justify introduction of challenged evidence because (1) the presumption is inapplicable in pharmaceutical products liability cases; (2) the presumption does not apply to defeat insufficiencies in direct testimony obtained from a physician; (3) Abbott would be able to rebut the heeding presumption with Dr. Kaplan's testimony that he

does not know what he would have done with respect to prescribing Maryann Depakote because he does not recall her circumstances; and (4) Abbott would be able to rebut the presumption by showing that Dr. Kaplan was aware of the risk that Depakote could cause spina bifida but prescribed it anyway. Id., 5-7. Even if the evidence has some relevance, Abbott argues that it will be unduly prejudicial. Id. at 5.

Plaintiffs should be permitted to argue that other warnings would have been heeded. Moreover, the testimony provided by Abbott does not demonstrate that Dr. Kaplan would not have heeded any other warning. Admission of evidence relating to other alleged inadequacies should not be unduly prejudicial or confusing, the parties will be able to argue what Dr. Kaplan stated would have caused him to make a different prescription decision and what did not.

A New Jersey trial court has applied the heeding presumption in the pharmaceutical context. *In re Diet Drug Litig.*, 895 A.2d 480, 489-91 (N.J. Super. 2005). A heeding presumption may be applicable to claims of failure to warn of the dangers of pharmaceuticals. *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 267 (N.J. Super. Ct. App. Div. 2008). The court did not decide the circumstances in which the heeding presumption would be appropriate. Id. at 267 n. 40. The court did note, however, that, even in the pharmaceutical context, the heeding presumption serves to reinforce the basic duty to warn, to encourage manufacturers to produce safer products, and to alert users to the hazards arising from the use of those products. Id. at 267. Moreover, the heeding presumption incentivizes manufacturers to abide by their duty to provide adequate warnings. Id. Thus, the suggestion that the heeding presumption is inapplicable as a general rule in the pharmaceutical context is inaccurate.

This case is further complicated by the fact that Dr. Kaplan did offer testimony. The presumption is usually applicable in circumstances in which the plaintiff lacks the ability to prove by direct evidence that a proper warning, if given, would have been heeded. Id. at 268. The *McDarby* court suggested that the heeding presumption would be unnecessary where the plaintiff obtained deposition testimony from his treating physician. "But here, direct evidence in the form of the deposition testimony of *McDarby's* treating physician existed, rendering use of a presumption unnecessary." *McDarby v. Merck & Co.*, 401 N.J. Super. 10, 82, 949 A.2d 223, 268 (App. Div. 2008)[3]

There is deposition testimony from Dr. Kaplan here too, but, according to Abbott's own reading of the deposition transcript, Dr. Kaplan was unable to recall the specifics of Maryann's treatment or to state what he would have done had different warnings had been given. Motion, 6. Thus, even if a deposition was obtained it was not useful on this issue. There is no material distinction between this case and that justifying the heeding presumption; it is as 'necessary' here as it was in *McDarby* because, as it happens, plaintiff does not have the ability to prove directly that a proper warning if given would have been heeded.[4]

Abbot points us to a last issue here. Defendants may obviate the heeding presumption by presenting evidence that reasonable minds could differ with respect to whether a warning, if given, would have been heeded. *In re Diet Drug Litig.*, 895 A.2d 480, 492 (N.J. Super. 2005). Abbott says it has already presented that evidence, that I need only decide now if it is enough to withstand a motion for directed verdict, and if so, I can in

[3] However, the court found that there was sufficient evidence for the trial court to direct a verdict in the plaintiff's favor on causation, so it found no material error. *Id.*

[4] That is, I reject Abbott's position that the mere fact that Kaplan's' deposition was taken obviates the presumption. T2 95 et seq.; 101 The rationale for the presumption would exist if Kaplan were in a coma, had amnesia, and so on, and his failure of memory here is the functional equivalent.

effect delete the heeding presumption now. But I think Abbott has to present the evidence at trial; and it remains unclear to me whether, even were I to agree that Abbott has presented a sufficient quanta of evidence, the jury nevertheless has the final say on whether reasonable minds can differ and so decides whether or not the presumptions is in the case. The matter will have to be resolved on way or the other at a jury instruction conference.

#15 **Bar evidence re financial condition**

Ruling: Moot. The parties agree that financial condition such as would be relevant for punitive damages is not admissible in the first phase of trial. Defendant does not object to marketing budget, sales growth, and so on, coming in to show the asserted economic motivation for defendant's actions.

#16 **Exclusion of witnesses**

Ruling: Moot.

Plaintiff's motions

1. Plaintiff's Psychiatric Background

Ruling: Grant in part & deny in part.

Plaintiff asks the court to exclude any history or details of: (1) abuse that plaintiff suffered as a child; (2) plaintiff's husband's alleged gambling problems; (3) plaintiff's suicide attempts, suicidal thoughts or statements; or (4) plaintiff's thoughts or statements relating to harming her children. Plaintiff argues that it is undisputed that she suffered from a psychiatric condition and was prescribed Depakote for that reason. Plaintiff does not object to the admission of that information, but seeks to bar the specific details listed above

because they are irrelevant, inflammatory and bear a substantial risk of prejudicing or confusing the jury.

Defendant argues that evidence of plaintiff's risk of harming herself or others is relevant because it relates to whether she took Depakote at all (what Abbott terms the "product i.d." issue) and to the degree to which she needed treatment for her condition. With regard to plaintiff's suicidal thoughts, defendant argues that that evidence has a direct impact on the type of medicine a doctor would prescribed to plaintiff. Tegretol, an alternative drug, is not effective for patients with suicidal thoughts. Mooney Decl., Ex.6, 80:25 - 84:4. Given that plaintiff claims defendant should have instructed doctors to prescribe Depakote only if other, less dangerous drugs, were not effective, evidence that plaintiff was at risk of committing suicide or harming her children, and that she had been hospitalized for psychiatric conditions and treated by multiple doctors, is relevant to prove that Dr. Kaplan might have prescribed Depakote even if he had read the more extreme warning.

Evidence regarding plaintiff's abusive mother, her husband's gambling problems, and her physically violent children is not relevant to show that her condition was sufficiently extreme that her doctor would have prescribed Depakote despite the severe side effects because that evidence does not relate to plaintiff's behavior. The type of drug taken by plaintiff would not impact the behavior of her mother, husband or children, and thus would not impact the doctor's choice of drugs. Additionally, this information is distracting and prejudicial; even if it were mildly relevant to show plaintiff's level of stress, the prejudicial impact of the evidence strongly argues excluding it.

2. Alternative Causes of Plaintiff's Injuries

Ruling: Deny.

Plaintiff claims that defendant's causation experts have admitted that Depakote was a factor in causing the birth defects at issue in this case. Because New Jersey law requires that a plaintiff only prove that Depakote was a "substantial factor" in causing plaintiff's injuries, plaintiff asks I bar defendant from introducing evidence or argument about alternative causes of plaintiff's daughter's spina bifida. According to plaintiff, evidence regarding alternative causes of the injury may cause the jury to think that plaintiff must prove that Depakote was 100% the cause of plaintiff's daughter's injuries.

Defendant disagrees, noting an expert has ruled out Depakote as a cause. Mooney Decl., Ex. 10, 85:23-86:3. (750 mg dose that plaintiff allegedly took during her pregnancy was not a significant factor). There are assertedly other reasons for the medical condition in this case. Mooney Decl., Ex. 16 (genetic history). And defendant offers other factors that may have played a role in plaintiff's daughter's condition, including: lack of folic acid during the first trimester; plaintiff's obesity; plaintiff's diabetes; plaintiff's potential ingestion of Percocet during her pregnancy; and plaintiff's stressful life. All this evidence is patently relevant to the substantial cause analysis (assuming expert testimony ties it to spina bifida) and I will not bar its introduction.

3. Evidence of Plaintiff's or Dr. Kaplan's Negligence or Fault

Ruling: Grant as to plaintiff, deny as to Dr. Kaplan.

Plaintiff desires the exclusion of evidence that plaintiff was negligent in taking or using Depakote, that Dr. Kaplan was negligent in prescribing Depakote, and "any argument or evidence regarding any knowledge or information available to, told to, or given to Maryanne Dotegowski concerning any alleged risk of Depakote prior to her pregnancy." The motion suffers from not identifying specific evidence, and evidentiary rulings likely will

have to be made on a case by case basis at trial. But the rulings provided now should help the parties prepare for trial.

Plaintiff stated at her deposition that Dr. Kaplan did not disclose the reported 1-2% spina bifida risk, did not ask plaintiff if she was having "sexual relations," if she was using birth control, or if she was trying to get pregnant, and did not warn her about becoming pregnant while taking the drug. Mooney Decl., Ex.4, 46:5-11; 52:18-20; 182:17-183:5. Presumably, defendant might attempt to offer this evidence to show that Dr. Kaplan would not have adequately informed plaintiff of the risks of using Depakote, or would have prescribed Depakote regardless of the level of warnings provided on the product label. Defendant has the right to use evidence to show that plaintiff's injuries would have occurred regardless of an improved warning label.

Abbott's argument suggesting *plaintiff* may have negligently contributed to the risks of her daughter's birth defects is not coherent. Abbott suggests that it is unclear whether plaintiff even took Depakote because she "failed to report her Depakote use to at least eight healthcare providers during two hospital stays between 1997 and 1998." Def's Opp, 23:7-9. But if she didn't take the drug, she couldn't have *negligently* taken the drug. Defendant also argues that if plaintiff "knew about the risk of birth defects and decided to take the medicine anyway, a jury would be within its purview to find that the chain of proximate causation has been broken." Not so. Plaintiff's access to the drug is entirely dependent on her doctor, the learned intermediary. There is no evidence plaintiff made an independent decision to take the drug, or would have had a basis to do so, or that there is any standard of care relating to such a putative independent decision.[5] This evidence should be excluded.

[5] The only evidence that might indicate contributory negligence on plaintiff's behalf is evidence that she lied to Dr. Kaplan about the possibility that she might get pregnant, or whether she was using birth control pills, etc.

Abbott's Motion on Bifurcation re Punitive damages

This motion seeks to add an additional phase to the usual two phase procedure involving punitive damages: to defer consideration of whether Abbott is guilty of the punitive precursors (malice, fraud, and oppression) until after a decision on compensatory damages. At argument on January 9, 2015, I noted my tentative determination to deny the motion because I could not identify evidence which would only be relevant to the punitive precursors but not to liability for compensatory damages. Nor could anyone else at argument. But it did become clear that the parties were in general agreement that at end of the end of liability phase, closing arguments, instructions, and jury verdict would only be devoted to compensatory damages, to be followed if appropriate by (if any such exist) evidence which only goes to the existence of the precursors, and then further deliberations on the precursors, which if one of them is found to be true, would lead to the last (and usual) phase devoted to punitive damages as such. I do not object to this, but repeat my alert to the parties that we must schedule the time for all these phases within the time set aside for trial.

Abbott's Motion re Bifurcation of Statute Of Limitations Issues

I. Choice of Law

Under New Jersey Law, the statute of limitations for products liability or personal injury claims is two years. New Jersey provides for a special tolling provision, however, in cases involving injuries to minors. Under NJ Rev Stat § 2A:14-21 (2013), a plaintiff may bring a products liability or personal injury claim within two years of his or her 18th birthday.

None of the evidence that defendant lists on page 23 of its opposition suggests that plaintiff engaged in any potentially negligent behavior.

> California's Code of Civil Procedure §340.4 states that
> An action by or on behalf of a minor for personal injuries sustained before or in the course of his or her birth must be commenced within six years after the date of birth, and the time the minor is under any disability mentioned in Section 352 shall not be excluded in computing the time limited for the commencement of the action.

Plaintiff argues that there is a conflict of law between New Jersey and California and that New Jersey law applies. Defendant urges New Jersey law.

California courts apply the governmental interest analysis to resolve conflicts of law. *Kearney v. Salomon Smith Barney, Inc.*, 39 Cal.4th 95, 107 (2006). In the first of three steps, the court determines whether the relevant law of the potentially affected jurisdictions is the same or different. Here New Jersey provides for a general two year statute of limitations, but then provides a separate tolling provision that applies when the plaintiff is a minor. Under California law, the statute simply sets forth a different limitations period for personal injury related claims brought by or on behalf of minors. Plaintiff notes that the conflict, therefore, is not between two statutes of limitations, but between the California statute of limitations and the New Jersey tolling provision. This is a distinction without a difference. If NJ Rev Stat § 2A:14-21 did not exist, plaintiff's claims would be subject to a two-year statute of limitation in New Jersey, which would also conflict with California's six-year, modified-for-minors, limitation. The end result in this case is that plaintiff's claim expires in California in 6 years and expires in New Jersey in 2 years after the age of majority. This is a conflict, regardless of the sources of law that create the conflict.

Once a conflict of law is identified, courts examine each jurisdiction's interest in applying its own law under the circumstances of the particular case. *Ashland Chemical Co. v. Provence*, 129 Cal.App.3d 790 (2005) held California's statute of limitations barred a contract claim even when the terms of the contract specifically stated that Kentucky law applied:

> California is the only interested state. Statutes of limitation are designed to protect the enacting state's residents and courts from the burdens associated with the

> prosecution of stale cases in which memories have faded and evidence has been lost. *McGee v. Weinberg* (1979) 97 Cal.App.3d 798, 804 (1979). Here California courts and a California resident would be protected by applying California's statute of limitations because California is the forum and the defendant is a California resident. Applying California's statute of limitations would thus advance its underlying policy. In choice of law terms, California has an "interest" in applying its law. In contrast, Kentucky has no interest in having its statute of limitations applied because here there are no Kentucky defendants and Kentucky is not the forum.

Id. 794. Here none of the parties is a California resident and all relevant facts and actions occurred outside of California. While this modifies California's interests, it does not affect the state's interest in protecting California courts from the "burdens associated with the prosecution of stale cases." Id.

New Jersey also has an interest in applying its law to this case because plaintiff is a New Jersey resident and the actions at issue in this case (e.g., plaintiff's mother's ingestion of Depakote) occurred in New Jersey. New Jersey has long expressed a desire to protect the personal injury claims of its minors. A statutory tolling provision for minors has been in place since 1799. *LaFage v. Jani*, 166 N.J. 412, 424 (2000). Although historically the tolling provision did not apply to all causes of action, recent case law has expanded the application to claims such as wrongful death and medical malpractice based on the express interest of protecting New Jersey minors from the adverse consequences of their ignorance of legal matters. *Id.* 430. Plaintiff is a New Jersey minor, and thus New Jersey's express interest in protecting its minors is a factor here.

Because both California and New Jersey have interests in applying their respective laws, I must compare the two interests to determine "which state's interest would be more impaired if its policy were subordinated to the policy of the other state." *Bernhard v. Harrah's Club*, 16 Cal.3d 313, 320 (1976). While plaintiff acknowledges that most courts have found

that the forum state has a greater interest in seeing its statute of limitations applied,[6] plaintiff argues that in unusual situations, such as these, the default is defeated.

Plaintiff cites *Ledesma v. Jack Steward Produce, Inc.* 816 F.2d 482 (1987), where a California court applied an Arizona statute of limitation to a case filed by a California plaintiff, against an Arkansas defendant, relating to an auto accident that occurred in Arizona. Arizona had enacted a special statutory period for claims related to highway accidents that was longer than the period provided for similar claims in California. *Id.* 485. The court acknowledged that California has an interest in protecting its courts from stale claims, but noted that that interest was "equally balanced" by California's interests in allowing its resident plaintiff to recover for injuries sustained in a state that would have recognized her claim as timely. *Id.* 487. Citing CCP § 351, the court noted that California is willing to be flexible with regard to limitations periods when the plaintiff is a California resident. Furthermore, the court stated that Arizona's interests would be significantly impaired if the court did not apply the Arizona statute. The court noted that by enacting its special statute of limitations for personal injury claims arising out of highway accidents, Arizona was attempting to deter careless driving on its highways by creating a longer liability period. Id. at 486.

Plaintiff argues that not only is *Ledesma* on point, but there is even less reason to apply California's limitations period in this case because plaintiff is not a California resident. But because Dotegowski is not a California resident, California's interest in protecting its forum from stale claims is not balanced against California's interest in helping its resident plaintiff to pursue her claims: California has no interest in helping a New Jersey resident to take advantage of another state's limitations period, particularly considering that that plaintiff

[6] Plaintiff's Separate Submission Regarding the Issue of Statute of Limitations, p. 3 fn. 5; *see also* Defendant's Response p. 3 fn. 5.

chose to file her lawsuit in California. Further, New Jersey's desire to protect its minors is not akin to Arizona's desire to improve safety on the highways within its state boarder. Injuries to minors in New Jersey are not more or less likely to occur if California applies its own statutory period because New Jersey minors can always bring their claims in a New Jersey court. Plaintiff has chosen California as the forum for this case; if she wanted to avail herself of the protections of the New Jersey tolling provision, she could have brought her claims in New Jersey.

California's interest would be more impaired if its policy were subordinated to the policy of New Jersey, than vice versa. California's statutory period applies in this case.

II. Constitutionality of CCP § 340.4

Plaintiff resurrects an argument made in opposition to defendant's summary judgment motion that § CCP 340.4 is unconstitutional. Plaintiff refers to pages 24-26 of the previously filed opposition brief. Defendant refers me to its response to that argument.

Plaintiff's argument is cursory. Plaintiff points out that minors who sustained injuries before or in the course of birth are subject to a six year statute whereas all other claims for minors are governed by CCP § 352(a), which, like New Jersey, tolls claims until the minor is 18 years old. Plaintiff argues that this distinction violates several sections of the California Constitution (the equal protection clause, the right to jury trial, the right to open courts, the right to petition for redress of grievances, and due process) and the U.S. Constitution (due process and equal protection). Plaintiff objects that the distinction between the two types of claims is arbitrary and that the "purported rational" "does not justify such restrictions." Plaintiff does not describe this purported rational.

Defendant points out that a statute of limitations does not implicate a fundamental right. *Cal. Grocers Ass'n v. City of Los Angeles*, 52 Cal.4th 177, 208 (2011). The statute also does

not implicate the classification of a suspect class. Therefore the rational basis test applies, and CCP § 340.4 is constitutional if: (1) the statute has a legitimate purpose; and (2) the lawmakers reasonably believed the classification would promote that purpose. *Yoshioka v. Superior Court*, 58 Cal.App.4th 972, 987 (1997).[7]

Defendant notes a 1954 case in which a plaintiff argued that the 6 year statute of limitation did not apply to his birth injuries because the statute was not enacted until after his injuries had occurred. *Olivas v. Weiner*, 127 Cal.App.2d 597, 598 (1954). The court surmised that the legislature enacted the statute on the rational that "to permit such an action to be filed up to 22 years after the child's birth, i.e., within one year after it reached majority, placed an unreasonable burden upon the defendant to locate witnesses and to produce evidence in defense of the charges after the lapse of such a long period." *Id.* Thus, the legislature "decided that six years was a reasonable time within which to bring such an action." *Id.* Although the *Olivas* court did not cite any legislative history to support its conjecture as to the rational basis behind the six year statute, defendant asserts that it is sufficient for a court to surmise a "plausible reason." *See Hoffman v. U.S.* 767 F.2d 1434, 1437 (9th Cir. 1985).

Another "plausible" reason for enacting differing statutory periods is that injuries occurring before or at the time of birth involve the child's mother. Statutes protecting minor's claims until they reach the age of majority are written to protect the interests of children who are likely unaware of the legal process and ignorant of their obligation (or opportunity) to pursue a claim. But when injuries occur prior to birth, the adult mother, who is likely aware of the injuries as they occurred while the child was *in utero*, can bring the claims on behalf of the child. Provided that the discovery rule applies (in case the injuries

[7] Actually, it does not matter if lawmakers ever considered the reason, and the "court's own rational speculation" is enough. *Johnson v. Dep't of Justice*, No. S209167, 2015 WL 363184, at *6 (Cal. Jan. 29, 2015).

are not apparent immediately) there is no need to extend the statutory period until the child becomes an adult. The adult mother is present to bring the claims on the child's behalf. This case is an example of just such circumstances. Thus, there are at least two rational reasons that support the creation of two different statutory time periods. On this record the constitutional challenge fails.

III. Practicalities of a Bifurcated Trial

I have asked the parties to submit witness lists with time estimates in order to evaluate the wisdom of ordering a bifurcated trial on the statute of limitations issue. I am familiar with the issue, and many of the underlying facts, from earlier work on Abbott's summary judgment motion, and I find the fact issue is susceptible to an early determination, with relatively little investment of time and effort. Given the discovery to date, the parties should now be ready for the bifurcated trial (scheduling issues aside). The witness lists suggest a few days of testimony.[8] A defense verdict resolves the case, and while a plaintiffs' verdict does not, I would expect it to lead to constructive settlement discussions. The motion for a bifurcated trial is granted and I will set dates at the next case management conference.

Dated: February 2, 2015

Curtis E.A. Karnow
Judge of The Superior Court

[8] It is not clear why plaintiff has most of witness listed, but even counting those that putatively relate to Plaintiff's knowledge, it comes in at about 7 hours, and at least some of that overlaps with Abbott's estimate of a bit under 5 hrs. There is no reason to think the experts or Abbott witnesses listed by plaintiffs have anything to do with the issue of Ms. Dotegowski's knowledge, or when she ought to have known, of Abbott's alleged wrongful conduct.

CERTIFICATE OF ELECTRONIC SERVICE
(CCP 1010.6(6) & CRC 2.260(g))

I, Ericka Larnauti, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On February 2, 2015, I electronically served the attached ORDER RE: MOTIONS IN LIMINE AND TO BIFURCATE (PUNITIVE DAMAGES & STATUTE OF LIMITATIONS) via File & ServeXpress on the recipients designated on the Transaction Receipt located on the File & ServeXpress website.

Dated: February 2, 2015

T. Michael Yuen, Clerk

By: _____
Ericka Larnauti, Deputy Clerk